IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Dario NERI et al.

Serial No.: 09/194,356 Group Art Unit: 1642

Filed: September 2, 1999 Examiner: Alana M. Harris

For: ANTIBODIES TO ED-B DOMAIN OF FIBRONECTIN, THEIR CONSTRUCTION AND USES

RESPONSE

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sincere appreciation is expressed to Examiner Harris for the courteous and helpful interview of October 23, 2003, including the invitation midway therein to Examiner Helms who was also most helpful in, it is believed, resolving the issues raised by the Examiner. The following summarizes the interview.

It is believed agreed that all claims would be allowed upon presentation of a declaration summarizing the scientific proof which establishes that prior art antibody BC-1 does not bind to the ED-B domain of the B^+ isoform of fibronectin (FN). Such a declaration by co-inventor Luciano Zardi is being filed herewith.

The Zardi Declaration is believed self explanatory. It summarizes the scientific evidence from the Carnemolla 1992 reference of record and Example 3 of the above-identified application, which establish that BC-1 does not bind to the ED-B domain of the B^+ isoform of FN. The confusion here was created by EP 344134, relied on by the Examiner, which incorrectly states that BC-1 does bind to the ED-B domain. EP 344134 has as its sole inventor coinventor, Luciano Zardi of this application. Dr. Zardi is also the last named author on Carnemolla 1992. In the latter publication, the authors state:

> Given this specifity, we assumed that the epitope recognized by the mAb BC-1 was localized within the ED-B sequence (Carnemolla et al.,1989). However, we now demonstrate that this epitope is localized within the type III repeat 7 (which precedes the ED-B) and that it is cryptic in FN molecules lacking the ED-B, while it is unmasked in molecules containing this sequence.

In other words, Zardi was incorrect in EP 344134 and subsequent to the latter's filing, has scientifically established that BC-1 does not bind to the ED-B domain but, rather, binds to an adjacent domain of the B^+ isoform, i.e., type III repeat 7.

Dr. Zardi carefully explains in his declaration the data on which this conclusion is based. Thus, it is respectfully submitted that this application is now in condition for allowance.

As for the matter raised in item 2 of the advisory action of June 24, 2003, Applicants have rendered this matter moot by deleting "and only" from dependent claim 34. This deletion is made only to expedite prosecution, especially since claim 34 is a dependent claim. It is clear from the specification, e.g., the data in example 3, among other disclosures, and as discussed by Dr. Zardi, the antibodies of this invention are specific to the EDB domain and do not bind, for example, to adjacent domains. These data provide the clear "contemplation" by the inventors of the concept embodied in the previous version of claim 34. Nevertheless, the matter is now moot.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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